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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,848	01/14/1999	TERUAKI SEKINE	SEKINE I	8123
1444 7590 07/03/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007 and 14 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 14, 19-27, 31, 32, 34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 19-27, 31, 32, 34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/15/2007 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13,14,19-27,31,32,34,36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (US Pat. 5,296,353) in view of Babbitt et al. (US Pat. 5,766,920), Ochoa et al. (U.S. Pat. 5,443,983), the acknowledged prior art, Wallace et al., Santamaria et al. and Sekine et al.

Ochoa et al. (US Pat. 5,296,353) teach activation of autologous T-lymphocytes with anti-CD3 (soluble or solid phase bound), such as OKT3, and cytokines, including IL-2, for treatment of cancers and diseases of viral etiology such as those caused by HIV, cytomegalovirus and Epstein Barr virus (See entire document, especially, Column 3, lines 32-50, Column 7, lines 54-68, Column 8, lines 1-35, Column 11, lines 29-54, Column 12, lines 15-54).

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Babbitt et al. teach activation of autologous T-lymphocytes (including that taken from peripheral blood of virally infected patients) with OKT3 and cytokines, including IL-2, for treatment of tumors or viral pathogens, including herpesvirus (herpes simplex virus and cytomegalovirus), Epstein Barr virus and HIV (See entire document, especially, Column 2, lines 22-68, Column 3, Column 7, lines 40-49, Column 20, lines 53-68, Column 21, lines 1-16). It is disclosed that solid phase OKT3 may be used but that soluble OKT3 is preferred (Column 12, lines 1, 2).

Ochoa et al. (U.S. Pat. 5,443,983) teach a method of developing LAK activity in lymphocytes comprising contacting lymphocytes with IL-2 and an anti-CD3 antibody and a method of administering the same suspended in a phosphate buffered saline supplemented with human serum albumin to an AIDS patient (Column 11, lines 49-68, Column 12, lines 1-50, Claims 1-8).

Applicant acknowledges that T-cells are involved in cellular immunity against cancer and viruses (Specification, Pgs. 1, 2). Further, it is acknowledged that lymphocytes, including T-cells and NK cells, can be activated and stimulated by IL-2 and that lymphocytes can be activated and stimulated with IL-2, with or without CD3 antibodies, including against viruses, such as, EBV and CMV (Specification, pgs. 3,4).

Wallace et al. disclose activation of T-cell precursors from the circulation of seropositive individuals with IL-2 and that the same are effective against autologous EBV transformed cells (Page 1012, Abstract).

Santamaria et al. disclose cytomegalovirus primed peripheral blood mononuclear cells from seropositive subjects which are stimulated by anti-CD3 coated onto polystyrene beads plus interleukin-2 and that polystyrene coated with antibodies can induce the long term-growth of

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antigen specific T-cell lines in the absence of specific antigen and feeder cells (Page 1, Abstract, Pages 4-7).

Sekine et al. discloses that cultivation of T lymphocytes from peripheral blood lymphocytes with immobilized anti-CD3 (OKT3) and IL-2 induces a rapid proliferative response and that the immobilized form of anti-CD3 proved better for expansion than soluble anti-CD3 (Page 73, Summary, Page 74, Page 77, Discussion).

The prior art discloses compositions, methods of preparing and methods of using activated autologous lymphocytes which are derived from virally infected patients and activated and proliferated by the combination of anti-CD3 antibodies in soluble or solid phase and interleukin -2, where the viral infection can be HIV, cytomegalovirus and Epstein Barr virus. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose excluding cytomegalovirus-infected patients or the use of anti-CD3 in solid phase. However, the prior art amply suggests the same as the prior art discloses the activation of autologous lymphocytes which can be used to treat viral infections, including viral infections other than cytomegalovirus, such as herpes simplex and Epstein Barr virus, which lymphocytes are activated by interleukin-2 and anti-CD3; that the use of solid phase anti-CD3 results in better proliferation than soluble anti-CD3; and the suspension of lymphocytes activated with interleukin-2 and anti-CD3 which are suspended in phosphate buffered saline and albumin. As such, it would have been well within the skill of one of ordinary skill in the art to prepare activated autologous T-lymphocytes from patients having viral infections other than cytomegalovirus, with the expectation that the activated autologous T-lymphocytes would be effective against said viral infections. Further, it would have been well within the skill of one of ordinary skill in the art to use solid phase anti-CD3 rather than soluble anti-CD3 with the

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expectation that suitable numbers of activated lymphocytes could be obtained at a faster rate.

Finally, it would have been well within the skill of one of ordinary skill in the art to administer the activate autologous lymphocytes in a carrier containing phosphate buffered saline and albumin with the expectation that the same would be a suitable carrier.

The Applicant's arguments have been duly considered but they are deemed unpersuasive for the reasons of record, including that set forth in the Final Office Action (6/16/2006) and the Advisory Action (5/21/2007) (said advisory action was in response to the latest amendment and reply of 2/15/2007 and responded to the arguments of the Applicant set forth therein).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### **Conclusion**

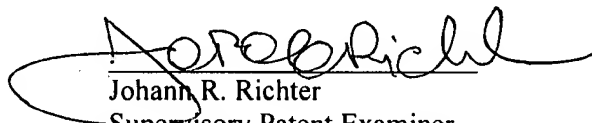
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
June 24, 2007

  
Johann R. Richter  
Supervisory Patent Examiner  
Technology Center 1600